The Nutraceutical Company
nutRamax
LABORATORIES, INC.

April 6, 1999

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Written Comments on Proposed Rule 21 CFR Part 101
Docket Number 98N-0826
Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements
Position: Against extending rule to dietary supplements

Dear Madam/Sir:

This letter will serve as our comments for the above-referenced proposed rule relating to the use of dietary supplements of health claims based on authoritative statements.

We believe that for health claims, conventional foods and dietary supplements **should not** be subject to the same standards and procedures. Nutrients in conventional foods are either already present or are added in small amounts, however these amounts are small compared to the concentrated amounts of nutrients and ingredients in most dietary supplements. Conventional foods have nutrients in only small trace amounts. That raises several concerns relating to the safety and effects of the ingredients in dietary supplements compared to those in conventional foods. Dietary supplements are not consumed for food value or taste. Dietary supplements are consumed to affect structure and function. Unlike conventional foods, dietary supplements may have side effects other than food type allergic reactions and therefore require more rigid standards.

Under the proposed rule, any company may be able to make a health claim although their product may not be the same or bioequivalent to the actual ingredient or combination of ingredients that were used in the study that the health claim is based upon. We believe that the reason for differences among ingredients is due to the lack of manufacturing standards for dietary supplement ingredients and products. Currently the required GMPs are food GMPs that do not ensure batch to batch consistency for dietary supplements. The GMPs for dietary supplements should be closer to those standards used in the pharmaceutical industry. There appears to be

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little batch to batch consistency for most dietary supplement products, especially herbal products, and many do not have validated assay methods to ensure ingredients are consistent and in the amounts that are claimed on the label.

There is so much inconsistency from product to product in the dietary supplement market and many companies are simply relying on Certificate of Analyses from suppliers who often use little or no standards and are located in countries outside the United States such as China. Many of these companies implement little or no quality control programs and rely simply on statements from their suppliers. There is a great deal of inconsistency because of the limited amount of checks and balances for dietary supplements and many products do not contain what is claimed on their label. If you apply the rule for conventional foods to dietary supplements you will have a flood of products that use this loophole to make unsubstantiated claims for their product and therefore injure the consumer by spending money on a product that does not live up to its claims or worse yet actually cause harm to that consumer due to the lack of control.

We also have a concern since the reliance for the health claim is based upon published authoritative statements from a scientific body of the United States such as the NIH, NAS or CDC. It may take several years for these government scientific bodies to study certain dietary supplement ingredients in the doses that are normally found in the market. IRB approved studies conducted by qualified research institutions and published in peer reviewed journals should be accepted as an authoritative body. Even the FDA agrees that the benefit from this particular proposed rule will come from the increased availability of the information provided by health claims. Consumers should also have access to truthful information by other IRB approved studies conducted by qualified research institutions and published in peer reviewed journals.

In summary, we would ask that you seriously re-consider allowing this rule to be applied to dietary supplements for the following reasons:

1. Conventional foods generally contain trace amounts of nutrients compared to much larger and concentrated amounts of nutrients and ingredients in dietary supplements.
2. Little or no batch to batch consistency due to lower manufacturing standards for dietary supplements.
3. Dependence upon ingredients information from suppliers who might use little or no standards.
4. Danger of dietary supplements not containing what is claimed on their label and the potential to harm the consumer.

Our suggestion would be to develop separate regulation for dietary supplements health claims which include the proper consumer protections such as pharmaceutical GMPs including validated assay methods and at least one clinical study that is IRB approved, conducted by qualified research institutions and published in peer reviewed journals.

We appreciate the opportunity to comment on this proposed rule. If you should have any questions, please do not hesitate to call.

Very truly yours,

Robert W. Henderson, PD
President

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